UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Provigil, Nuvigil

Program	Prior Authorization
Medication	Provigil (modafinil), Nuvigil (armodafinil)
Markets in Scope	Arizona, California, Colorado, Hawaii, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	2/2010
Pharmacy and Therapeutics Approval Date	1/2021
Effective Date	3/2021

1. Background:

Modafinil (Provigil) and armodafinil (Nuvigil) are wakefulness-promoting agents for oral administration. Both products are approved by the Food and Drug Administration (FDA) to improve wakefulness in patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, and shift work disorder. Modafinil has been shown to be beneficial in the treatment of excessive sleepiness in patients with idiopathic hypersomnia, treatment of fatigue associated with multiple sclerosis, and in the augmentation therapy for the treatment of depression.

2. Coverage Criteria:

A. <u>Narcolepsy, Obstructive Sleep Apnea, Shift Work Disorder, or Idiopathic Hypersomnia (off-label)</u>

1. <u>Authorization Criteria</u>

a. **<u>One</u>** of the following:

- Diagnosis of narcolepsy
- Diagnosis of excessive sleepiness due to obstructive sleep apnea
- Diagnosis of excessive sleepiness due to shift work disorder (circadian rhythm sleep disorder, shift work type)
- Diagnosis of idiopathic hypersomnia

-AND-

b. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Authorization will be issued for 12 months.

B. Fatigue due to MS (off-label)

1. All of the following:

   a. Diagnosis of multiple sclerosis (MS)

   -AND-

   b. Patient is experiencing fatigue

   -AND-

   c. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Authorization will be issued for 12 months.

C. Adjunctive Therapy for the Treatment of Major Depressive Disorder or Bipolar Depression (off-label)

1. Initial Authorization

   a. Treatment-resistant depression, defined as both of the following:

      (1) Diagnosis of one of the following:

      - Major depressive disorder (MDD)
      - Bipolar depression

      -AND-

      (2) History of failure, contraindication, or intolerance to at least two antidepressants from different classes (e.g., SSRIs, SNRIs, bupropion)

      -AND-

   b. Used as adjunctive therapy

   -AND-

   c. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Authorization will be issued for 12 months.

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2. Reauthorization

   a. Documentation of positive clinical response to therapy

   -AND-

   b. Used as adjunctive therapy

   -AND-

   c. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References

1. Provigil [package insert]. North Wales, PA: Cephalon, Inc.; July 2019.
2. Nuvigil [package insert]. North Wales, PA: Cephalon, Inc.; July 2019.
3. Morgenthaler TI, Kapur VK, Brown T, et al. Standards of Practice Committee of the American Academy of Sleep Medicine. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep. 2007;30(12)1705-116.
4. Rammohan KW, Rosenberg JH, Lynn DJ, et al. Efficacy and safety of modafinil (Provigil) for the treatment of fatigue in multiple sclerosis: a two center phase 2 study. J Neurol Neurosurg Psychiatry 2002;72:179-183.
5. Zifko UA, Rupp M, Schwarz S, et al. Modafinil in treatment of fatigue in multiple sclerosis. Results of an open-label study. J Neurol 2002;249:983-987.
6. Goss AJ, Kaser M, Costafreda SG, Sahakian BJ, Fu CH. Modafinil Augmentation Therapy in Unipolar and Bipolar Depression: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. J Clin Psychiatry 74:11, November 2013.
7. Practice guideline for the treatment of patients with major depressive disorder. Third edition. American Psychiatric Association. Arlington, VA. October 2010.

Program	Prior Authorization- Provigil, Nuvigil

Change Control	
Date	Change
2/2010	New policy
9/2010	Removed requirement of the trial of Provigil prior to Nuvigil approval.
6/2011	Annual Review. Added Nuvigil indications to section II, Indications. No criteria changes.
6/2012	Annual Review. Added generic requirement for Provigil in product list table.
6/2013	• Converted policy to new UHC enterprise wide formatting. • Added additional confirmation symptoms for OSA initial therapy (see sections 1.1 and 2.1 of OSA initial therapy) • Created reauthorization criteria for SWSD • Added requirement for MS fatigue that requires combination with standard educational therapies • Created reauthorization criteria for MS fatigue • Created quantity limit exception criteria for both Provigil and Nuvigil • Created reauthorization criteria for Narcolepsy • Seperated Narcolepsy and Idiopathic Hypersomnia criteria • Created reauthorization criteria for and Idiopathic Hypersomnia
9/2013	• For Provigil/Nuvigil, revised narcolepsy criteria from "submission of sleep study confirming diagnosis of narcolepsy" to "diagnosis of narcolepsy as confirmed by sleep study" • For Provigil, revised idiopathic hypersomnia criteria from "submission of sleep study confirming diagnosis of idiopathic hypersomnia" to "diagnosis of idiopathic hypersomnia as confirmed by sleep study"
12/2014	Added prior authorization criteria for Provigil (modafinil) for adjunctive treatment for the treatment of major depressive disorder or bipolar depression
10/2016	Updated policy template. A few of the AND statements were changed to OR statements in the quantity limit section.
12/2016	Updated wording in quantity limit sections
3/2017	Changed all authorization durations to 12 months.

8/2017	Updated clinical criteria to only diagnosis for narcolepsy, obstructive sleep apnea, and shift work disorder and trial/failure of armodafinil if requesting modafinil. Removed quantity limit sections. Changed Provigil to modafinil throughout policy. Updated background.
3/2018	Modified the language around the diagnosis for shift work disorder to include circadian rhythm, shift work disorder, to match the ICD10 code. Updated off-label sections to allow for use of armodafinil.
1/2019	Updated criteria for idiopathic hypersomnia and multiple sclerosis since these are included in the DX2RX program.
1/2020	Annual review, updated references.
1/2021	Annual review, updated references.